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No. 06-372

Supreme Court, U.S.
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IN THE
Supreme Court of the United States

FERRING B.V. AND AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

BARR LABORATORIES, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondent Barr Laboratories, Inc. states that it is a wholly owned subsidiary of Barr Pharmaceuticals, Inc., which is a publicly held company.

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INTRODUCTION

The petition for certiorari in this case is wholly contrived: it presents questions that were never raised below, conjures up contrived "circuit splits," and assails the Federal Circuit's treatment of regulations that have been subsequently amended. Tellingly, petitioners have little to say about *this case*, instead launching for the first time a broadside on the doctrine of inequitable conduct itself. These arguments are waived and, thus, the petition should be denied.

As petitioners all but concede, the Federal Circuit broke no new legal ground in this case, but merely applied its own settled precedent to the unique facts presented. Both the "'determination of whether withheld information meets a threshold level of materiality and intent to mislead,'" and the "'weighing of materiality and intent in light of all of the circumstances to determine whether the applicant's conduct is *so culpable* that the patent should be held unenforceable,'" are quintessentially fact-specific exercises trusted to the sound discretion of the district court. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362-63 (Fed. Cir. 2003) (quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1366 (Fed Cir. 2001) (in turn citing *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998))) (emphasis in original). Now, having lost in the district court, lost on appeal, and failed to obtain a single dissent from denial of rehearing *en banc*, petitioners suddenly, for the first time, object to the entire edifice of inequitable conduct doctrine. This Court does not sit to consider issues of first impression.

At bottom, it is petitioners who seek a radical departure in the law. Notwithstanding the fact that the Federal Circuit was created as a national court to bring uniformity to our patent system, petitioners attempt to turn back the clock and have this Court review stale "circuit splits" pre-dating the Federal Circuit's creation.

Far from presenting an issue of pressing national importance in which there is deep division within the Federal Circuit, the petition itself demonstrates that the inequitable conduct doctrine is well-settled and is the subject of substantial agreement within the Federal Circuit. In any event, the radical constriction and, ultimately, "abolition" of the inequitable conduct doctrine that petitioners ask this Court to consider is a matter better suited for Congress than the courts (even if petitioners had presented their arguments below, which they did not).

Petitioners' lamentations regarding the supposed "broadening" of the inequitable conduct doctrine over the past twenty years are particularly misplaced in this case. In the district court, respondent Barr Laboratories, Inc. ("Barr") introduced a substantial volume of evidence demonstrating that (1) the applicants had submitted declarations from interested persons without disclosing those interests—*declarations the inventor himself substantially drafted despite the examiner's request for "non-inventor" declarations*; (2) these declarations were material because they were submitted to overcome prior art rejections, and thus went directly to patentability, while the omitted information went directly to the declarants' credibility; and, (3) the applicants' omission of the declarants' interests was plainly intentional. Petitioners, in turn, had ample opportunity to adduce additional facts but declined to do so. The district court's finding of inequitable conduct was compelled by the undisputed facts, and the Federal Circuit's affirmance was likewise compelled by *Refac International Ltd. v. Lotus Development Corp.*, 81 F.3d 1576 (Fed. Cir. 1996), and *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182 (Fed. Cir. 1993). However, petitioners failed to so much as question these precedents in their briefing below (including their separate petitions for rehearing *en banc*), and

conspicuously omit any citation to them in their petition for certiorari.

This case also presents no occasion to consider petitioners' purported "conflict" between Federal Circuit precedent and the Patent and Trademark Office's ("PTO's") post-1992 regulations on materiality for the simple reason those regulations are not applicable to this case. The patent-in-suit was prosecuted under the *pre-1992* regulations, which codified the "reasonable examiner" standard employed by the Federal Circuit below. The Federal Circuit here, as in every other case involving patents prosecuted under the pre-1992 regulations, simply applied "the pre-1992 language regarding materiality." App. 10a n.6. Because this case involves the pre-1992 PTO regulations, it presents no issue of continuing importance warranting this Court's review.

For all their hyperbole, petitioners have not presented a single issue worthy of this Court's discretionary review. Given the unique facts of this case and petitioners' failure to identify either an issue of exceptional importance or a genuine conflict within the Federal Circuit warranting this Court's intervention, this case presents no occasion to jettison well-settled precedent or engage in a wholesale revision of the doctrine of inequitable conduct. Thus, the petition should be denied.

COUNTERSTATEMENT OF THE CASE

A. Factual Background

United States Patent No. 5,407,398 ("the '398 patent") claims the oral administration of "1-deamino-8-D-arginine vasopressin," commonly known as DDAVP or desmopressin. App. 2a. Ferring was the exclusive licensee of U.S. Patent No. 3,497,491 ("the '491 patent" or "Zaoral patent")—which claimed the DDAVP compound itself—and had been manufacturing and marketing desmopressin acetate products for intranasal and

intravenous administration since the 1970's. *See id.* at 3a; Fed. Cir. Joint Appendix ("J.A.") 2189.

Shortly before the expiration of the Zaoral patent (and, with it, Ferring's monopoly), Ferring filed the first of several patent applications that ultimately issued as the '398 patent. *See* J.A. 4497. The '398 patent issued on September 10, 1991, after a lengthy prosecution that included multiple rejections by the PTO and an unsuccessful appeal to the Board of Appeals & Interferences ("the Board"). The application resulting in the '398 patent was the third one filed by petitioner Ferring and inventor Hans Vilhardt claiming the same invention, the first two having been rejected. App. 3a & n.1. After the first two rejections, Vilhardt—represented by Ferring counsel—appeared at a preliminary interview regarding the third application and disputed the scope of the prior art. *Id.* at 3a. The PTO "'suggested that applicants obtain evidence from a *non-inventor*' to support their interpretation." *Id.* (quoting J.A. 3460) (emphasis added by the court). Thereafter, Vilhardt submitted declarations from himself and Dr. Paul Czernichow seeking to distinguish the prior art. Although Vilhardt disclosed his own ties to Ferring, Czernichow's 28-page CV failed to mention that he had received research funding from Ferring *that year*. *Id.* at 3a-4a. [1]

Despite the declarations, the examiners rejected claims based on the prior art (specifically Ferring's '491 patent), noting that "'[a]s Applicants are the exclusive licensee of the Zaoral ['491] patent, it is *obviously expeditious* for Applicants to argue that "peroral" referred

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[1] At the time of his declaration, Czernichow was funded by Ferring for his desmopressin research (the drug at issue). J.A. 2901-02. He was researching desmopressin *with the wife of Ferring's CEO*, Dr. Anna Fjellestad, authoring an article with her on that topic. *See* J.A. 2935; J.A. 3816-17; J.A. 3820.

to in the ['491] patent referred only to'" absorption rather than ingestion through the mouth. App. 4a (quoting J.A. 4390) (emphasis added). The applicants requested reconsideration and yet another examiner reaffirmed the rejections, finding the applicants had failed to distinguish the '491 prior art patent. *Id.*

Following an appeal to the Board and its rejection based on the '491 patent in combination with additional prior art (the "Vavra paper"), Vilhardt wrote to Ferring's counsel that "everything now depends on our ability to deal with the Vavra paper." J.A. 3749. In preparing to "deal with the Vavra paper," Vilhardt contacted at least two Ferring consultants regarding additional declaration evidence: Dr. Iain Robinson and Professor Tomislav Barth. Thereafter, applicants submitted additional declarations from Czernichow, Robinson, and Barth to distinguish the additional prior art that, in combination with the '491 patent, had been the basis for a rejection by the Board. App. 5a-6a. Although each of these declarants had extensive ties to Ferring (Robinson was research director from 1985-86 and a consultant from 1986-89, and Barth worked on Ferring projects between 1984-87), these relationships were concealed from the PTO. *Id.* Petitioners have conceded the "applicant knew of the connections between Ferring and Drs. Barth and Robinson, but did not disclose them." Aventis Fed. Cir. Reh'g Pet. 5.

Although the examiner specifically requested "*non-inventor*" declarations, it is undisputed that Vilhardt substantially drafted the declarations. App. 6a-7a; *see also* J.A. 5544-45; J.A. 3756. "Vilhardt admitted that he gave Barth 'some lines,' telling him "what he should describe in the affidavit." App. 7a (quoting J.A. 5544). Likewise, Robinson conceded that he did not author

portions of his declaration. *See* J.A. 2868.[2] And Czernichow conceded he also did not write all parts of his declaration. *See* App. 24a n.16. Indeed, apart from his signature, Czernichow did not write *anything* in either of his two declarations to the examiner. *See* J.A. 2902; J.A. 2922; J.A. 2925. It is undisputed that the PTO was unaware of Vilhardt's role in drafting the supposedly "non-inventor" declarations. *See* App. 7a.

Following the submission of these declarations, the PTO finally allowed the applicants' claims. *Id.* Nothing in the file history offers any explanation for the PTO's change in position, except Ferring's submission of the declarations. *See id.*; J.A. 3719.

B. District Court Proceedings

Petitioners sued Barr for infringement pursuant to 35 U.S.C. § 271(e). Petitioners' privilege logs, disclosed during litigation, confirmed that Czernichow, Robinson, and Barth were "Ferring Consultants." App. 15a. Although Vilhardt initially denied having contact with these declarants, "when confronted with the privilege log" indicating that "he had contacted each of the declarants and that he sent Barth and Robinson 'draft declarations,'" he recanted, *id.* at 24a, thereafter acknowledging his substantial role in prosecuting the '398 patent, *see* J.A. 5544-45. Indeed, documents petitioners attempted to

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[2] At the time of his PTO declaration, Robinson admittedly had no "particularized expertise" in desmopressin, and had performed no research on drug delivery systems or on the absorption of peptides into the gastrointestinal tract. J.A. 2871. He subsequently expressed surprise that he had been asked to submit such a declaration, adding that he had "no idea" why he was contacted for a declaration or that his declaration would be used to help Ferring obtain a patent. J.A. 2868-69. Indeed, at his deposition, Robinson specifically contradicted the statement in his declaration regarding the Vavra paper. J.A. 2877.

withhold as privileged confirmed Vilhardt's role in obtaining the declarations, as well as his understanding of the importance of the declarations to obtaining the patent. *See* J.A. 5544-45; J.A. 3749; J.A. 5516.

The undisputed evidence also demonstrated that Vilhardt was aware of the declarants' relationships with Ferring. Specifically, "Vilhardt was aware that Robinson was Ferring's pre-clinical research director while Vilhardt was serving as a consultant to Ferring" on the very drug at issue. *See* App. 19a. Likewise, Vilhardt was aware of Barth's affiliation with Ferring. *See* App. 20a.[3]

Barr moved for summary judgment based on inequitable conduct and non-infringement and submitted the following undisputed evidence:

- Ferring's applications had twice been rejected based on the Zaoral patent. J.A. 4514; J.A. 4544.
- The examiner characterized the applicants' arguments trying to distinguish Zaoral as "*expeditious*" given their "obvious[]" interest in the matter. J.A. 4390 (emphasis added).
- Applicable PTO guidelines provided that a declarant's interest is a factor the examiner may consider. Manual of Patent Examining Procedure ("MPEP") § 716(3) (1983-1987).
- In considering Ferring's third application, the examiner requested "evidence from a non-inventor to the same effect." J.A. 3460.

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[3] Ferring concedes that Barth worked in Vilhardt's laboratory. *See* App. 20a; Ferring Fed. Cir. Br. 28. As noted above, Aventis concedes that Vilhardt knew of the connections between Ferring and both Barth and Robinson, but did not disclose them to the PTO. Aventis Fed. Cir. Reh'g Pet. 5.

- The applicants and their attorneys submitted Vilhardt's declaration and CV, which disclosed his former employment relationship with Ferring. J.A. 3531; J.A. 3589.
- At the same time, applicants submitted Czernichow's declaration and *28-page* CV without mentioning his history as a Ferring consultant. J.A. 2901-02; J.A. 3601-32; J.A. 3755.
- The application was again rejected and the Board affirmed based on Zaoral and the Vavra paper. J.A. 4390-91; J.A. 3096-3105.
- To overcome the Board's Vavra-paper rejection, Ferring submitted additional declarations criticizing that reference from Czernichow, Barth and Robinson (who was not even an expert in the relevant field, *see* J.A. 2871, and later contradicted his declaration, J.A. 3703; J.A. 2877), all without disclosing their former employment and consulting relationships with Ferring. J.A. 3701-08.
- The inventor, Vilhardt, *drafted all or some of the so-called "non-inventor" declarations* provided by Czernichow, Robinson, and Barth. *See* J.A. 3756-57; J.A. 2902; J.A. 2922; J.A. 2868; J.A. 5544.

In response to Barr's motion, petitioners failed to submit *any evidence whatsoever* (such as a simple declaration from Vilhardt) to rebut Barr's *prima facie* case or otherwise suggest a good faith explanation for the applicants' actions, effectively conceding that there were no factual disputes.

From these undisputed facts, the district court granted summary judgment to Barr on inequitable conduct. Applying the Federal Circuit's decisions in *Refac* and *Paragon*, it concluded that the applicants' failure to disclose the declarants' interest was material and drew the only *reasonable* inference the summary judgment record would allow—that the applicants' omission of the

declarants' interest was intentional. The district court observed that a finding of materiality and intent was not, in and of itself, enough. The court must "then go on to determine 'whether the applicant's conduct is *so culpable* that the patent should be held unenforceable.'" App. 68a (quoting *Dayco Prods.*, 329 F.3d at 1363). Here, the district court found, based on the undisputed facts, that "[t]he deceit was practiced over a long period of time by more than one person and appears to have been outcome determinative." *Id.* at 68a-69a. Because "the entire record presents clear and convincing evidence of an intent to mislead the examiners, even viewing the evidence, as it must be viewed, in the light most favorable to Plaintiff[s]," the district court held the patent unenforceable. *Id.* at 68a.[4]

C. Federal Circuit Proceedings

The Federal Circuit affirmed. The court applied the traditional two-step approach to inequitable conduct. *See* App. 9a. Under that approach, a party alleging inequitable conduct must first make a threshold showing of materiality and intent. Then the district court must balance both showings and determine, within its discretion, whether when considered together they constitute inequitable conduct. Here, the court of appeals reviewed the district court's "determination that there were no genuine issues of material fact with respect to the issues of materiality and intent" *de novo*, while the overall finding of inequitable conduct was reviewed for an abuse of discretion. *Id.* at 10a, 25a.

With respect to materiality, the court observed that the rules for PTO examiners specifically recognize that

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[4] The district court also granted summary judgment to Barr on non-infringement. The Federal Circuit did not reach that independent holding, which would provide an alternative ground for affirmance. *See* App. 9a & n.5.

"'[a]ffidavits or declarations should be scrutinized closely,'" and that "'[t]he affiant's or declarant's interest is a factor which *may be considered*.'" App. 11a-12a (emphasis added) (quoting MPEP); *see also id.* at 62a. Citing *Refac* and *Paragon*, the court concluded "a declarant's past relationship[] with the applicant are material if (1) the declarant's views on the underlying issue are material and (2) the past relationship to the applicant was a significant one." *Id.* at 13a-14a. The Federal Circuit agreed with the district court that the declarations were "highly material" because they were relied on by the PTO to overcome patentability objections. *Id.* at 14a. The court further agreed that the past relationships were significant—they were not isolated and were not confined to the distant past. *Id.* at 15a-16a. The identities of the declarants would have been significant to the examiners because they "specifically requested 'non-inventor' affidavits." *Id.* at 16a. Based on the totality of the record, the Federal Circuit found it was "clear" that "the examiners were concerned about the objectivity of those providing declarations and their relationship to Ferring, and that they communicated this concern to the applicants." *Id.* at 17a. As in *Refac*, the court found the applicants were on notice as to the materiality of the declarants' ties to Ferring. *Id.* The Federal Circuit rejected petitioners' argument that "they could have, at trial, presented evidence to raise a fact issue concerning either the significance of the experts' views or the significance of past relationships." *Id.* Having failed to present such contrary evidence in response to the summary judgment motion, the court held petitioners "cannot raise a genuine issue of material fact by speculating as to what evidence might have been introduced at trial." *Id.*

Turning to the issue of intent, the Federal Circuit declined to "lay down a general rule as to when intent may be or must be inferred from the withholding of material information by an applicant." App. 19a. Rather,

it applied a settled three-part test for determining intent: (1) whether the applicant knew of the information; (2) whether the applicant knew or should have known of the materiality of the information; and (3) whether the applicant has provided a credible explanation for withholding the information. *Id.* (citing *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348,1354 (Fed. Cir. 2005); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997)). Here the undisputed evidence demonstrated that the applicants "knew of significant past relationships of at least two of the declarants." *Id.* The undisputed evidence also demonstrated that the applicants were "on notice" that the examiners were concerned about the identity of the declarants. *Id.* at 20a. Finally, petitioners offered no credible explanation whatsoever for the omission. The Federal Circuit rejected unsubstantiated "possible benign explanations" supported by nothing more than attorney argument and raw speculation. *Id.* at 21a; *see id* at 23a. Rather, "in order to create a genuine issue, [petitioners] bore the burden of submitting an affidavit from Vilhardt to contradict the movant's evidence of intent." *Id.* Applying this Court's holding in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986), the court held that petitioners "cannot create a genuine issue by suggestions that Vilhardt *might* have proffered favorable evidence at trial." *Id.* (emphasis in original) (citing *Paragon*, 984 F.2d at 1191). The only reasonable inference to be drawn from the summary judgment record was that "the past relationships were deliberately concealed." App. 24a.

The court reviewed the district court's ultimate finding of inequitable conduct for an abuse of discretion. App. 25a (citing *General Elec. Co. v. Joiner*, 522 U.S. 142, 143 (1997); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc)). Considering the materiality of the declarations and the declarants' affiliation with Ferring, the fact that there

was not simply a single omission but "multiple omissions over a long period of time—a fact that heightens the seriousness of the conduct," App. 25a-26a, and the evidence of intent, the Federal Circuit held the district court had not "abused its discretion in finding inequitable conduct," *id.* at 26a. Judge Newman dissented.

Petitioners each filed their own petition for rehearing and rehearing *en banc*. The petitions were denied. App. 86a-89a. Although two judges (in addition to Judge Newman) noted that they would rehear the appeal *en banc*, no judge filed a dissent from denial. App. 89a.

REASONS FOR DENYING THE WRIT

The petition is not worthy of this Court's review for three simple reasons. *First*, petitioners' issues were not presented to, much less decided by, the Federal Circuit and are thus waived. The radical restructuring, if not abolition, of the well-settled patent-law doctrine of inequitable conduct is a matter that obviously should be presented to and passed on by the Federal Circuit—*the court specifically created by Congress to provide nationwide uniformity in patent law*—before this Court's intervention is remotely warranted. In any event, petitioners' arguments are better suited to Congress than the courts.

Second, there is no deep conflict within the Federal Circuit's inequitable conduct jurisprudence requiring this Court's intervention. Petitioners' reliance on contrived "circuit splits" from a quarter of a century ago—before Congress created the Federal Circuit to bring uniformity to patent law—is misplaced. Indeed, this case marks nothing more than the application of settled patent-law principles to a unique set of undisputed facts. The applicants engaged in a pattern of deception before the PTO and offered no evidence of a credible explanation for their concealment of obviously material facts. Distilled to its essence, petitioners' charge is that a finding of inequitable conduct is warranted only "where there is real

misconduct before the PTO," Pet. 11, and that the conduct here was not "real misconduct." That claim is refuted by the record and this Court, of course, does not sit to review factual determinations—much less those committed to a district court's sound discretion.

Third, even if there were any merit to petitioners' claim of a conflict between PTO practice and Federal Circuit precedent on the narrow issue of "materiality" (which there is not), this case would present an exceptionally poor vehicle in which to address it. This case involves the PTO's *pre-1992* regulations, which petitioners concede "articulated the same standard for materiality" applied by the Federal Circuit. Pet. 18. Moreover, there can be no serious question that the intentional omissions here—which go directly to credibility of the very declarations submitted to overcome a patentability objection—were material in any meaningful sense of the word.

II. Petitioners' Arguments That The Inequitable Conduct Doctrine Should Be Dramatically Narrowed Or Abolished Were Not Presented Below And Are Waived.

The petition begins and ends with the premise that the inequitable conduct doctrine has "strayed far from [its] equitable roots" and that, as such, the doctrine requires a substantial pruning, if not outright abolition. The problem for petitioners, however, is that they made no such arguments below and thus these arguments are waived. *See, e.g.*, *Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 56 n.4 (2002); *United States v. United Foods, Inc.*, 533 U.S. 405, 417 (2001); *Pennsylvania Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212-13 (1998); *United States v. Lovasco*, 431 U.S. 783, 788 n. 7 (1977); *United States v. Ortiz*, 422 U.S. 891, 898 (1975). This Court does not sit to dispense such strong medicine when the lower court has not so much as been asked to consider an issue. To the contrary, this Court's

"traditional rule" precludes a grant of certiorari "when the question presented was not pressed or passed upon below," *United States v. Williams*, 504 U.S. 36, 41 (1992) (internal quotations omitted), precisely because the Court "sits as a court of review," not a court of first impression, *Duignan v. United States*, 274 U.S. 195, 200 (1927).

One will search petitioners' court of appeals briefs (as well as their petitions for rehearing and rehearing *en banc*) in vain for even the faintest suggestion that the court should consider the radical realignment of the inequitable conduct doctrine proposed here, much less its abolition. Petitioners never asserted any conflict between the Federal Circuit's inequitable conduct jurisprudence and this Court's decisions in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), and *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945). Indeed, neither case is cited in any of the six briefs (including their petitions for rehearing and rehearing *en banc*) petitioners collectively filed below.

To be clear, petitioners accepted the principles espoused by the court below, just not the application of those principles to these facts. Both petitioners recited the Federal Circuit's precedent governing inequitable conduct, noting that "materiality and intent are questions of fact," Aventis Fed Cir. Br. 21; *see* Ferring Fed. Cir. Br. 41, without suggesting that the "contours" of inequitable conduct had become too broad. Rather, both merely argued that the *evidence* did not support a finding of inequitable conduct under settled precedent. *See* Aventis Fed. Cir. Br. 22-24; Ferring Fed. Cir. Br. 49-52.

Likewise, petitioners never argued below that the Federal Circuit was applying a test for inequitable conduct that conflicted with PTO regulations and practice, and they did not advocate any of the "stricter" standards for materiality that they suggest would be preferable to prevailing Federal Circuit caselaw. To the

contrary, petitioners expressly argued that the "relevant [pre-1992] PTO regulation in force" required application of a "reasonable examiner" standard, Aventis Fed. Cir. Br. 35; *see also* Ferring Fed. Cir. Br. 42—the very standard applied by the Federal Circuit. App. 10a & n.6.

Nor did petitioners raise these broad, sweeping issues in their petitions for rehearing or rehearing *en banc*. Their rehearing petitions argued that: (1) the panel had "misapprehended pivotal facts," Aventis Reh'g Pet. 5, or had mischaracterized the relationship between the applicant and the declarants, Ferring Reh'g Pet. 9; (2) adopted an allegedly new "knew or should have known" standard for assessing intent in contravention of Federal Circuit precedent, Aventis Reh'g Pet. 9; *see* Ferring Reh'g Pet. 9; and (3) misapplied the summary judgment standard, Aventis Reh'g Pet. 11; Ferring Reh'g Pet. 14. At most petitioners suggested that this case was a departure from settled Federal Circuit precedent, not that the so-called "vast modern expansion of the doctrine" should be reconsidered, Pet. 13, much less abolished, *see id.* at 28.

In any event, such an argument is better suited for Congress than the courts. Congress can legislate the doctrine of inequitable conduct "out of existence any time it chooses." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997). However, given the lengthy history of the doctrine—predating creation of the Federal Circuit itself—"[t]he various policy arguments now made by [petitioners] are thus best addressed to Congress, not this Court." *Id.* "Congress is far better equipped than the judiciary to amass and evaluate the vast amounts of data bearing upon an issue as complex and dynamic as that presented here," namely the effect of expanding or contracting the inequitable conduct doctrine on the vitality of the patent system. *Turner Broad. Sys., Inc. v. F.C.C.*, 512 U.S. 622, 665-66 (1994) (internal quotations omitted).

Even if there were any merit to petitioners' arguments (which there is not), the Court should await, as is its custom, the views of lower courts so that an issue is fully vetted and focused before it steps in to settle it. After all, certiorari jurisdiction is "to be exercised sparingly, and only in cases of peculiar gravity and general importance, or in order to secure uniformity of decision." *Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916). The Court's traditional practice of requiring that an issue be presented or passed on before undertaking consideration is all the more warranted here where the court below is specifically charged by Congress with "reducing the potential for widespread uncertainty and nonuniformity" in patent law. *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 475 (Fed. Cir. 1991). "That objective was one of the fundamental purposes for establishing the Federal Circuit." *Id.* (citing S. Rep. 97-275, 97th Cong., 1st Sess. 5, *reprinted in* 1982 U.S. Code Cong. & Admin. News, 11, 15. H.R. Rep. 97-312, 97th Cong., 1st Sess. 23). Indeed, as this Court repeatedly has made clear, "Congress conferred exclusive jurisdiction of all patent appeals on the Court of Appeals for the Federal Circuit, in order to provide nationwide uniformity in patent law." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) (internal quotations omitted); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). It would thus be extraordinary for this Court to address an issue that falls squarely within the Federal Circuit's patent-law mandate without first obtaining the views of the Federal Circuit on that issue. Because petitioners have waived the issues they now advance, the petition should be denied.

III. The Federal Circuit Properly Applied Settled Patent Law Principles And There Is No Circuit Split.

Petitioners' assertion of a circuit split is a canard. To manufacture their "split," petitioners rely on *twenty-four*

year old cases (and older) in which, prior to the creation of the Federal Circuit, the regional circuits espoused competing standards for assessing materiality and intent in patent cases. However, the Federal Circuit was created precisely to resolve such conflicts and bring uniformity to patent practice. *See Bonito Boats*, 489 U.S. at 162; *Electronics for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed. Cir. 2005); *Kennedy v. Wright*, 851 F.2d 963, 966 (7th Cir. 1988) ("The Federal Circuit's exclusive jurisdiction under § 1295(a)(1) was created, after all, so that there could be a uniform jurisprudence of patent law."). After its creation, it promptly resolved the conflicts asserted by petitioners.

In *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362-63 (Fed. Cir. 1984), the court identified three different standards for materiality courts had previously employed and held that "the [pre-1992] PTO 'standard' is an appropriate starting point for any discussion of materiality, for it appears to be the broadest, thus encompassing the others, and because that materiality boundary most closely aligns with how one ought to conduct business with the PTO." To be sure, the court did not adopt a rigid approach, recognizing instead that materiality is a threshold issue of fact and that "'materiality' and 'culpability' are often interrelated and intertwined, so that a lesser showing of the materiality of the withheld information may suffice when an intentional scheme to defraud is established," and vice versa. *Id.* at 1363. Likewise, in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988), the *en banc* Federal Circuit addressed the conflicting standards of "intent" necessary to meet the threshold for proceeding to the second "balancing" portion of the inequitable conduct inquiry. The court held that "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate

sufficient culpability to require a finding of intent to deceive." *Id.* at 876. Simply put, there is no lingering circuit split, much less one of any consequence given the Federal Circuit's virtually exclusive jurisdiction in patent cases.

Moreover, since its decisions in *American Hoist* and *Kingsdown*, the Federal Circuit's inequitable conduct jurisprudence has remained uniform, yielding no deep divisions within that court. On the issue of materiality, the court has consistently applied the reasonable examiner standard to cases involving patents prosecuted under the pre-1992 PTO regulations, *as it did in this case. See* App. 10a & n.6; *see also Dayco Prods.*, 329 F.3d at 1363-64; *Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001); *Li Second Family Ltd. v. Toshiba Corp.*, 231 F.3d 1373, 1379 (Fed. Cir. 2000). Similarly, the so-called "sliding scale" theory bemoaned by petitioners has not given rise to any intra-circuit conflict. Indeed, the cases cited by petitioners were each decided unanimously. *See* Pet. 21 & n.9 (citing *Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002); *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1359 (Fed. Cir. 2003); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003); *Critikon*, 120 F.3d at 1257).

Likewise the relevance of whether an applicant "knew or should have known" about the materiality of omitted information to determining intent is a well-settled aspect of the Federal Circuit's inequitable conduct jurisprudence. *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006); *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1346 (Fed. Cir. 2005); *Brasseler*, 267 F.3d at 1376, 1380; *GFI*, 265 F.3d at 1275; and *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1375 (Fed. Cir. 2000). And with good reason. Absent an objective standard, inequitable

conduct could almost never be proven by circumstantial evidence, despite this Court's repeated admonition that direct evidence is not necessary. However, "[i]t is hornbook law that direct evidence of a fact is not necessary. 'Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'" *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986) (quoting *Michalic v. Cleveland Tankers, Inc.*, 364 U.S. 325, 330 (1960)); *see also Paragon*, 984 F.2d at 1189-90 ("'Smoking gun' evidence is not required in order to establish an intent to deceive."). Indeed, proof of an "[i]ntent to mislead [the PTO] does not require direct evidence," *Bristol-Myers Squibb*, 326 F.3d at 1239, and "the facts in inequitable conduct cases rarely include direct evidence of admitted deceitful conduct," *GFI*, 265 F.3d at 1274. Instead, "[i]ntent is generally inferred from the facts and circumstances surrounding the applicant's overall conduct, especially where there is no good faith explanation for a nondisclosure." *M. Eagles*, 439 F.3d at 1341. That is precisely what occurred here. Barr submitted uncontested circumstantial evidence, while Petitioners failed to even submit an affidavit denying that the applicants intentionally concealed the declarants' relationships with Ferring.

Petitioners' contention—repeated throughout the petition—that the information applicants omitted was not material because the PTO would not consider the declarants' bias as current and former Ferring consultants relevant to the patentability issues, is absurd. *See* Pet. 2, 7, 19, 22, 23, 24, 29. As the district court observed, "[t]he reluctance of the PTO to issue the '398 patent was evident. Each affidavit submitted in support of its issuance was thus highly material to the prosecution history." App. 68a. The Manual of Patent Examining Procedure itself makes clear that "[a]ffidavits or declarations should be scrutinized closely and the facts presented weighed with care. *The affiant's or declarant's*

interest is a factor which may be considered." Manual of Patent Examining Procedure § 716(3) (1983-1987) (emphasis added); *see also* MPEP § 716.01(d) (6th ed. 1995) (examiners "assessing the probative value" of a declaration "*must consider . . . the interest of the expert [declaration] in the outcome of the case*") (emphasis added). That should come as no surprise. Under common law stretching back to Blackstone's day, courts have recognized, for example, that it is appropriate to impute bias to prospective jurors in cases involving their private employers. *See, e.g., United States v. Wood*, 299 U.S. 123, 138 (1936) (citing Blackstone); *Crawford v. United States*, 212 U.S. 183, 195-96 (1909) (same). Thus, far from being "tangential," Pet. 22, these declarations were submitted *to overcome a patentability objection* that had resulted in numerous previous denials. The declarants' credibility was integral to the PTO's decision to allow the patent finally to issue. The PTO had clearly requested non-biased "non-inventor" declarations. The applicants provided the declarations without disclosing the declarants' relationships with Ferring while, at the same time, expressly disclosing Vilhardt's relationship. Worse, the inventor himself *actually drafted the declarations* in whole or in part. This is precisely the kind of concealment or misrepresentation that "has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed." *Kungys v. United States*, 485 U.S. 759, 770 (1988) (internal quotations omitted).

Given the applicants' egregious pattern of behavior and their failure to offer any evidence explaining the withholding of information, the district court in no way abused its discretion in finding the conduct inequitable. Moreover, whether the Federal Circuit (or the district court before it) properly determined that the thresholds for materiality and intent were properly met and that the conduct, considered as a whole, was inequitable, is an inherently fact-bound question. Because "[a] court of law,

such as this Court" is not "a court for correction of errors in fact finding," *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 336 U.S. 271, 275 (1949), the petition should be denied.

IV. This Case Presents No Ongoing Conflict Between Federal Circuit Precedent And PTO Regulations Because It Involves The PTO's Pre-1992 Regulations.

This case presents an exceptionally poor vehicle in which to consider petitioners' purported conflict between Federal Circuit precedent and PTO practice for the reason that it involves the PTO's *pre-1992* regulations. As petitioners concede, the pre-1992 version of 37 C.F.R. § 1.56 was "in effect at the time of the prosecution of the patent-in-suit." Pet. 1. Simply put, those regulations have been amended and are inapplicable to patents prosecuted after 1992. Given the limited lifespan of patents, application of the pre-1992 regulations is of little prospective importance. More fundamentally, there is no conflict between the pre-1992 regulations and Federal Circuit caselaw on materiality. To the contrary, the Federal Circuit has adopted the same "reasonable examiner" standard as the starting point in its inequitable conduct analysis. Indeed, the Federal Circuit *expressly applied that standard in this very case.*

A theme throughout the petition is that the Federal Circuit's inequitable conduct jurisprudence "interfere[s] with the PTO's ability to regulate practice before the agency." Pet. 3; *see id.* at 13, 27. But that bold assertion is simply false. The panel opinion could not be clearer: "For patent applications that have been prosecuted prior to 1992, we have held that '[i]nformation is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.'" App. 10a (quoting *Li Second Family*, 231 F.3d at 1379 (in turn quoting 37

C.F.R. § 1.56 (1989)).[5] The Federal Circuit "use[s] the pre-1992 language regarding materiality for evaluating patents that were prosecuted before [1992]." *Id.* 10a. n.6. Again, thus, petitioners' complaint is not with the standard for materiality articulated by the court of appeals in this case, but with the *application of that standard to these unique facts*. Petitioners concede as much. They note that in *American Hoist* the Federal Circuit adopted the standard invoked below and that the "pre-1992 Rule 56 *articulated the same standard for materiality*." Pet. 18 (*comparing American Hoist*, 725 F.2d at 1362, *with* 37 C.F.R. § 1.56(a) (1991)) (emphasis added).

Plaintiffs' solitary citation for the proposition that the Federal Circuit has declined to apply the PTO's materiality standard is *Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006). That unanimous decision, however, involved the PTO's *post-1992* regulations, not the regulation at issue here. *See id.* at 1314 (addressing whether "whether the new Rule 56 [is] essentially the same as the 'reasonable examiner' standard" of the old Rule 56). It is far from clear that the post-1992 regulations were intended to supplant the Federal Circuit's standards. In promulgating the new regulation, the PTO noted that: "Section 1.56 has been amended to present a clearer and

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[5] We know from the PTO's own procedures, that the interest of a declarant is necessarily important to a "reasonable examiner" because examiners are instructed that "[a]ffidavits or declarations should be scrutinized closely and the facts presented weighed with care. *The affiant's or declarant's interest is a factor which may be considered.*" MPEP § 716(3) (1983-1987) (emphasis added); *see also* MPEP § 716.01(d) (6th ed. 1995) (examiners "assessing the probative value" of a declaration "*must consider . . . the interest of the expert [declaration] in the outcome of the case*") (emphasis added).

more objective definition of what information the Office considers material to patentability. *The rules do not define fraud or inequitable conduct which have elements both of materiality and of intent.*" Duty of Disclosure, 57 Fed. Reg. 2021-02, 2024 (Jan. 17, 1992) (emphasis added). Indeed, in response to a comment suggesting that courts might interpret the duty of "candor and good faith" to require more than PTO rules require, the PTO stated that the rule was "modified to emphasize that there is a duty of candor and good faith which is broader than the duty to disclose material information." *Id.* at 2025.[6]

Even assuming there were any tension between the Federal Circuit's materiality threshold in the inequitable conduct context and the post-1992 regulations, the Court should await a case involving *those* regulations. That issue is simply not presented here, where the parties, the district court, and the Federal Circuit all agreed that the pre-1992 regulations applied. *See* App. 10a & n.6; App. 61a; Pet.1; Aventis Fed. Cir. Br. 35-36, 41 (noting the "relevant PTO regulation in force at the time of the prosecution of the '398 patent" was 37 C.F.R. § 1.56(a)

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[6] Petitioners' suggestion of a conflict between the doctrine of inequitable conduct and this Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001), is misplaced. *Buckman* rejected "*State-law* fraud-on-the-FDA claims" because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and thus are "impliedly *pre-empted* by, federal law." *Id.* at 348, 350 (emphasis added). The inequitable conduct doctrine arises out of *federal* law. And it does not, in and of itself, make an applicant *liable* for his fraud on the PTO. Rather, the court's authority to render a patent unenforceable for inequitable conduct is founded in the equitable principle that "'he who comes into equity must come with clean hands.'" *Dayco Prods.*, 329 F.3d at 1364 n.3 (quoting *Precision Instrument*, 324 U.S. at 814).

(1991)); Ferring Fed. Cir. Br. 42. In any event, the Federal Circuit *unanimously* decided *Digital Control* only a few months ago, after having deferred the issue for many years. *See, e.g., Dayco Prods.*, 329 F.3d at 1364; *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1109-10 (Fed. Cir. 2003); *PerSeptive Biosys., Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322 n. 2 (Fed. Cir. 2000); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1179 n. 8 (Fed. Cir. 1995). No decision in the intervening months has questioned that holding. As such, this Court's intervention would be premature and the petition should be denied.[7]

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[7] If the PTO believes that the Federal Circuit's recent unanimous decision in *Digital Control* is in conflict with its post-1992 regulations, it knows how to make its views known to that court (and, for that matter, this Court). Given that this case does not even implicate the PTO's post-1992 regulations, there is no basis for burdening the Solicitor General by requesting his views on this wholly private dispute.

CONCLUSION

For the foregoing reasons, this Court should deny the petition for writ of *certiorari*.

Respectfully submitted,

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